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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
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Washington, DC 20515-6115

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December 4, 2007

DENNIS B. FITZGIBBONS, CHIEF OF STAFF
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The Honorable Michael O. Leavitt
Secretary
U. S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

Under Rules X and XI of the Rules of the U.S. House of Representatives, the Committee on Energy and Commerce and the Subcommittee on Oversight and Investigations are investigating the Food and Drug Administration's (FDA's) management of drug safety issues. As part of this investigation, the Subcommittee sent you a letter on February 16, 2007, requesting production of documents pertaining to the pre-market review and post-market surveillance of the antibiotic telithromycin (Ketek).

On March 1, 7, and 29, April 4 and 25, May 17, and July 3, 19, and 24 and October 25, 2007, you sent partial responses to our initial request for production. A number of the documents contained within these productions, as well as information from third party sources, lead us to believe that FDA ignored evidence of false trial data in Study 3014. Furthermore, one or more FDA officials, through incompetence or worse, may have interfered with criminal investigations of private firms involved in this case.

Your staff recently arranged for Committee staff to interview Special Agent Robert West, Investigator Patti Smith, and Special Agent Robert Ekey, each of whom participated in the FDA investigation of fraud in Ketek Study 3014. In the course of reviewing documents recently made available to us, we learned that a third agent, Douglas M. Loveland, was also assigned to the investigation of Ketek (2006-TFM-709-0263). Please arrange for Committee staff to interview Mr. Loveland during the second or third week of December 2007.

The Honorable Michael O. Leavitt
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We appreciate your cooperation in arranging for the interviews of Agents West, Smith, and Ekey and look forward to hearing from you with regard to Special Agent Loveland. If there are any questions, please do not hesitate to contact David Nelson or Joanne Royce with the Committee staff at (202) 226-2424.

Sincerely,

A handwritten signature in blue ink, appearing to read "John D. Dingell", written over a horizontal line.

John D. Dingell
Chairman

A handwritten signature in blue ink, appearing to read "Bart Stupak", written over a horizontal line.

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ed Whitfield, Ranking Member
Subcommittee on Oversight and Investigations